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Published:

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- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

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26 January 2006

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: IMMUNOGENIC COMPOSITIONS FOR *STREPTOCOCCUS AGALACTIAE*

(57) Abstract: This application relates to Group B Streptococcus ("GBS") vaccines comprising combinations of GBS polypeptide antigens where the polypeptides contribute to the immunological response in a recipient. Preferably, the compositions of the invention comprise a combination of two or more GBS antigens, wherein said combination includes GBS 80 or a fragment thereof. In one embodiment, the combination may consist of two to thirteen GBS antigens selected from an antigen group consisting of GBS 80, GBS 91, GBS 104, GBS 184, GBS 276, GBS 305, GBS 322, GBS 330, GBS 338, GBS 361, GBS 404, GBS 690, and GBS 691.



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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/30032

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61K 39/385, 39/116, 39/00, 39/02, 39/38, 39/09
US CL : 424/197.11, 203.1, 192.1, 190.1, 184.1, 244.1

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 424/197.11, 203.1, 192.1, 190.1, 184.1, 244.1

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2004/041157 A2 (CHIRON CORPORATION) 21 May 2004 (21.05.2004), claims, and pages 4 and 5.	1-17



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T"

later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X"

document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y"

document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&"

document member of the same patent family

Date of the actual completion of the international search

09 November 2005 (09.11.2005)

Date of mailing of the international search report

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Name and mailing address of the ISA/US

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/30032

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
Please See Continuation Sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of any additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: 1-17

- Remark on Protest**
- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
 - ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
 - ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/30032

BOX III. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claim(s) 1-17, drawn to a composition comprising a combination of two or more GBS antigens comprising GBS 80 or a fragment thereof.

Group II, claim(s) 18, drawn to a method for the therapeutic or prophylactic treatment of GBS infection by administering the composition of invention I.

Group III, claim(s) 19-21, drawn to a method for the manufacture of a medicament by combining a GBS 80 antigen fragment thereof with at least one GBS polypeptide antigen.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Inventions I-III lack unity. The special technical feature of invention I is a composition comprising a combination of two or more GBS antigens comprising GBS 80 or a fragment thereof. However, such a composition was already disclosed in the prior art. For instance, CHIRON CORPORATION (WO 2004/041157 A2) disclosed a composition comprising a combination of GBS 80 having the amino acid sequence of SEQ ID NO: 2 and GBS 322 antigen. Thus, the product of invention I does not define over the prior art.

Although the product of invention I and the method of using the product of invention II and a method of making the product of invention III is a permitted combination under PCT Rule 13.2, in the instant case, since the product of invention I is already disclosed in the art, the special technical feature is not a unifying feature. Technically, the absence of special technical feature permits the separation of the method of using the product or the method of making the product from the product itself.

Continuation of B. FIELDS SEARCHED Item 3:

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/30032

DIALOG, WEST, MEDLINE, BIOSIS, EMBASE, Sequence databases
GBS 80, SEQ ID NO: 2, inventors' names